PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 257-Q-03-PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2007/001401	International filing date *(day/month/year)* 13 November 2007 (13.11.2007)	Priority date *(day/month/year)* 13 November 2006 (13.11.2006)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant Q-CORE LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 11 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   ☒ Box No. I   Basis of the report

   ☐ Box No. II   Priority

   ☐ Box No. III   Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   ☐ Box No. IV   Lack of unity of invention

   ☒ Box No. V   Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   ☐ Box No. VI   Certain documents cited

   ☒ Box No. VII   Certain defects in the international application

   ☒ Box No. VIII   Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 May 2009 (19.05.2009)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer **Simin Baharlou**
Facsimile No. +41 22 338 82 70	e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
EYAL BRESSLER
DR EYAL BRESSLER LTD.
LAZROM HOUSE 11 TUVAL ST.
RAMAT GAN, ISRAEL 52522

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	**24 SEP 2008**

Applicant's or agent's file reference	FOR FURTHER ACTION
257-Q-03-PCT	See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/IL07/01401	13 November 2007 (13.11.2007)	13 November 2006 (13.11.2006)

International Patent Classification (IPC) or both national classification and IPC

IPC: Please See Continuation Sheet
USPC: 715/741,744;604/9,67;346/43;700/90

Applicant

Q-CORE LTD.

1. This opinion contains indications relating to the following items:

☒   Box No. I   Basis of the opinion

☐   Box No. II ·   Priority

☐   Box No. III   Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐   Box No. IV   Lack of unity of invention

☒   Box No. V   Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐   Box No. VI   Certain documents cited

☒   Box No. VII   Certain defects in the international application

☒ · Box No. VIII   Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	22 August 2008 (22.08.2008)	TING ZHOU
Facsimile No. (571) 273-3201		Telephone No. (571) 272-4058

Form PCT/ISA/237 (cover sheet) (April 2007)

	International application No.
WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY	PCT/IL07/01401

Box No. I   Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a.   type of material

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b.   format of material

   ☐ on paper

   ☐ in electronic form

   c.   time of filing/furnishing

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in electronic form.

   ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Form PCT/ISA/237(Box No. I) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY	International application No. PCT/IL07/01401

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

    Novelty (N)

        Claims <u>2-4,26,28-29 and 38-39</u>   YES

        Claims <u>1,5-25,27,30-37 and 40-45</u>   NO

    Inventive step (IS)

        Claims <u>NONE</u>   YES

        Claims <u>1-45</u>   NO

    Industrial applicability (IA)

        Claims <u>1-45</u>   YES

        Claims <u>NONE</u>   NO

2. Citations and explanations:

Please See Continuation Sheet

Form PCT/ISA/237 (Box No. V) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY	International application No.
	PCT/IL07/01401

Box No. VII   Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 27 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Claim 27 recites "The GUI-IP of claim 27" in line 1. A claim can not be dependent upon itself. Claim 27 should have been recited as "The GUI-IP of claim 23".

Form PCT/ISA/237 (Box No. VII) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY	International application No. PCT/IL07/01401

Box No. VIII   Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 38-39 and 41 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 38-39 and 41 are indefinite for the following reason(s): Claims 38 and 41 recite "The user interface of claim 14" in the preambles; however, Claim 14 is claiming a method, not a user interface, therefore, the preambles of claims 38 and 41 should have read "The method of claim 14". Similarly, the preamble of claim 39 recites "The user interface of claim 38"; however, claim 38 is dependent upon claim 14, which is claiming a method, not a user interface, therefore, the preamble of claim 39 should have read "The method of claim 38".

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International application No.
PCT/IL07/01401

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Continuation of IPC:
G06F 3/00(2006.01);A61M 5/00(2006.01),31/00(2006.01);G01D 9/00(2006.01);G06F 17/00(2006.01)

V. 2. Citations and Explanations:
Claim 1 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches a method comprising the steps of obtaining a graphic user interface for infusion pump (GUI-IP) implemented in an infusion pump's control unit (CU) (infusion pump device comprising a display, as shown in Figure 1) (column 2, lines 6-8); obtaining an intuitively operable hierarchical array of operational pages (user selection of an item displayed on one page, or routine results in the display of a next/subsequent page/routine) (column 6, lines 17-45); interconnecting the same in a plurality of common infusion protocols (the display is used for displaying and managing operating conditions of the infusion pump) (column 3, lines 46-63); relating each of the pages to at least one stage of the infusion's protocol or to regulation of the same (each of the views shown on the GUI represent a routine for the infusion pump display) (column 6, lines 17-45); providing GUI-IP which comprises per each stage, one or more commands presenting only options that are possible in that stage (as shown by the different pages of the infusion pump display shown in Figures13a-13d for example, each of the pages displays different information and selectable prompts to the user) (column 6, line 17-column 7, line 9), wherein degrees of freedom in operating the CUs are reduced and number of unnecessary faults decrease to minimum (users can access only a limited amount of information on each page displayed on the GUI, as shown in Figures 13a-13d for example).

Claim 2 lacks inventive step under PCT Article 33(3) as being obvious over Meinzer and Numano. Meinzer teaches all of the limitations as applied to claim 1 above. However, although Meinzer teaches authorization in inputting infusion parameters (access to the infusion pump GUI is limited to authorized personnel) (Meinzer: column 6, lines 41-45), Meinzer fails to explicitly teach a plurality of levels of authorization. Numano teaches a graphical user interface that requires authorization to access (Numano: page 1, paragraph 0011) similar to that of Meinzer. In addition, Numano further teaches a plurality of authorization levels for accessing the parameters of the GUI (four user authorization levels) (Numano: page 3, paragraphs 0043-0047). It would have been obvious to one of ordinary skill in the art, having the teachings of Meinzer and Numano before him at the time the invention was made, to modify the infusion pump GUI of Meinzer to include the plurality of authorization levels for accessing the GUI, as taught by Numano. One would have been motivated to make such a combination in order to protect the security of personal information while allowing multiple users to access a database of information.

Claim 3 lacks inventive step under PCT Article 33(3) as being obvious over Meinzer and Numano. Meinzer, as modified, teach changing the levels of authorization via requesting identification means from the user (display user name and password input field) (Numano: Figures 3 and 7), inputting the identification means (user input of name and password) (Numano: Figures 3 and 7), analyzing the identification means (authenticating the user based on the user identification means) (Numano: Figures 3 and 7), switching the level of authorization (user-switching instruction) (Numano: Figures 3 and 7), inputting infusion parameters authorized only for high-level

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authority holders (the administrator has the highest level of authority for accessing the GUI) (Numano: page 3, paragraph 0048) and returning to the former level of authorization (access levels can be changed back upon inputting the corresponding user name and password for the previous level of authorization by following the steps displayed in Figure 7 of Numano).

Claim 4 lacks inventive step under PCT Article 33(3) as being obvious over Meinzer and Numano. Meinzer, as modified, teach wherein the step of providing the level of authorization is further comprising steps selected from a group consisting of doctor authorizing, nurse authorizing, medic authorizing, patient authorizing, administrator authorizing, inclusive authorizing or system designer authorizing (authorized hospital personnel, i.e. doctor, nurse, medic, etc.) (Meinzer: column 6, lines 41-45).

Claim 5 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches a method comprising step of obtaining unique icons and soft keys having intuitive interpretation (a soft key area 40 displaying a plurality of soft keys and the display of a plurality of icons, such as icons 72 and 74 for example) (column 3, lines 46-63 column 4, lines 41-52).

Claim 6 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches the step of changing their shape or location or size of the icons or soft keys (as shown from Figure 11b to 11c, the position of the stop icon 126 has changed) (Meinzer: column 9, lines 1-20).

Claim 7 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches a method comprising obtaining minimal degrees of freedom by displaying the minimal data required and providing minimal options for the user (as shown by the different pages of the infusion pump display shown in Figures 13a-13d for example, each of the pages displays information and selectable prompts for different routines to the user) (column 6, line 17-column 7, line 9).

Claim 8 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches the step of displaying the inputted field differently than other fields (inputted field, such as user input of selection of the rate field causes the rate field to displayed differently, i.e. highlighted) (column 10, lines 1-4).

Claim 9 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches the step of providing N buttons in addition to soft keys and thus avoiding accidental pressing on those buttons (the infusion pump provides other buttons, such as the buttons on the numeric keypad and button 116) (column 4, lines 2-40 and column 6, lines 3-7).

Claim 10 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches the step of activating the buttons after a predetermined of time the buttons are pressed (the function associated with the buttons are activated upon user pressing the button) (column 4, lines 2-40).

Claim 11 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches adapting the GUI-IP for operating two or more different infusion protocols (the medical infusion pump is adapted to multiple clinical settings and includes a plurality of flow channels) (column 1, line 66-column 2, lines 5).

Claim 12 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches a method comprising steps of providing minimal number of soft keys and adaptive icons (as shown in the figures, only a limited number of soft keys and icons are displayed on the GUI display) (column 3, lines 55-60 and column 4, lines 41-52) and displaying minimal number of navigating options using the icons and soft keys (as shown in the figures, only a limited number of prompts/options can be selected using the soft keys and icons) (column 3, lines 55-60 and column 4, lines 41-52).

Claim 13 lack novelty under PCT Article 33(2) as being anticipated by Zaleski. Zaleski teaches a method comprising step of inputting data according to medical competence and patient medical record (data is updated on the GUI according to information such as patient usage of medication, patient access to information and patient medical records) (page 2, paragraph 0020 and page 3, paragraphs 0023-0024).

Claim 14 lack novelty under PCT Article 33(2) as being anticipated by Zaleski. Zaleski teaches wherein the step of inputting infusion parameters is provided by step of inputting of parameters selected from a group consisting of number of dose, rate, volume, concentration, duration, medicine type or any combination thereof (parameters include fluid volume dispensed) (page 2, paragraph 0021).

Claim 15 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches a graphical user interface for infusion pump control unit (GUI-CIP) (infusion pump device comprising a display, as shown in Figure 1) (column 2, lines 6-8) comprising a plurality of hierarchical array of operation pages user selection of an item displayed on one page, or routine results in the display of a next/subsequent page/routine) (column 6, lines 17-45); a plurality of stages, each of which presented by at least one of the pages (each of the views shown on the GUI represent a routine for the infusion pump display) (column 6, lines 17-45), such that the pages present options that are possible in the stage only (as shown by the different pages of the infusion pump display shown in Figures 13a-13d for example, each of the pages displays different information and selectable prompts to the user) (column 6, line 17-column 7, line 9); and a plurality of commands, accessible to the user by graphic means, each of which enables the user to navigate from one stage to another (commands that facilitate user navigation between pages, i.e. user selection of soft keys to display a plurality of different routines and

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functions) (column 3, lines 34-46 and column 6, lines 17-45).

Claim 16 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches navigators, directing the user among the pages (soft keys associated with different routines and functions that can be selected by the user) (column 3, lines 34-46 and column 6, lines 17-45).

Claim 17 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches displayers presenting predetermined infusion parameters being intuitively interpreted (default fields for infusion parameters as shown in Figure 10b) (column 8, lines 7-16).

Claim 18 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches a plurality of N buttons, each of the button executes a singular command at a specific stage, so as to minimize the number of faults (the plurality of soft keys 36 shown in the soft keys area 40 in Figure 5) (column 3, lines 55-57).

Claim 19 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein N is an integer number in the range from 1 to 3 (as shown in Figure 5, 3 soft keys are displayed, namely the "Change Mode" soft key, "Label" soft key and the "Primary" soft key).

Claim 20 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein N is an integer number in the range of 2 to 6 (as shown in Figure 5, 3 soft keys are displayed, namely the "Change Mode" soft key, "Label" soft key and the "Primary" soft key).

Claim 21 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the buttons are activated by continuous push, so as it is operable only by a willful act (the function associated with the buttons are activated upon a continuous push, i.e. user pressing the button) (column 4, lines 2-40).

Claim 22 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the buttons are selected from a group consists of ON/OFF, Start/Stop and dose/prime (the "on/off" charge key) (column 4, lines 28-31).

Claim 23 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches at least one soft key configured to change infusion parameters and navigate among the interface pages (for example, the "Change Personality" soft key in Figure 8b can be selected to display a new page, i.e. subroutine to change the previous set of configuration parameters) (column 6, lines 17-40 and column 7, lines 38-53).

Claim 24 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the soft keys are finger-operated (user pressing the keys) (column 4, lines 28-31).

Claim 25 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the font of the pages is selected from a group consists of character and numbers in Latin letters, Hebrew letters, Arabic letters, Latin, Cyrillic, and Korean Hangul, Hiragana, Kanji, Katanga, in any known fonts or combination thereof (for example, as shown in Figure 5, the information is displayed using a known font in English, which uses Latin characters and numbers).

Claim 26 lacks inventive step under PCT Article 33(3) as being obvious over Meinzer and Milner. Meinzer teaches all of the limitations as applied to claim 15 above. However, Meinzer fails to explicitly teach wherein the pages are displayed by two or more languages, selected by the user. Milner teaches a graphical user interface for assisting medical patients (Milner: Figures 3-4) similar to that of Meinzer. In addition, Milner further teaches wherein the pages are displayed by two or more languages, selected by the user (selecting language pairs, such as English-Spanish) (Milner: column 8, lines 9-16 and further shown by the page displayed in Spanish in Figure 22). It would have been obvious to one of ordinary skill in the art, having the teachings of Meinzer and Milner before him at the time the invention was made, to modify the display of pages for an infusion pump GUI of Meinzer to include the display of pages in a plurality of different languages, as taught by Milner. One would have been motivated to make such a combination in order to allow doctors and patients who speak different languages to be able to clearly and easily communicate with each other.

Claim 27 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the soft key includes user programmable function keys (the soft keys can be selected to program the values of the selected functions) (column 8, lines 7-31).

Claim 28 lacks inventive step under PCT Article 33(3) as being obvious over Meinzer and Milner. Meinzer, as modified, teach wherein adapted to accept input using vocal commands (a voice component that allows patient commands, i.e. responses to be heard) (Milner: column 6, lines 25-38).

Claim 29 lacks inventive step under PCT Article 33(3) as being obvious over Meinzer and Milner. Meinzer, as modified, teach wherein the soft key is configured to accept input via a touch screen (touch sensitive screen provided for user input) (Milner: column 7, lines 13-18).

Claim 30 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein adapted to several treatment

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performed by the infusion pump (several modes for infusion) (column 11, line 62-column 12, line 5 and Figure 15), especially intermittent, PCA, TPN, continuous treatments or any combination thereof (infusion rates can be intermittent, i.e. the infusion can be paused, as shown in Figure 11c) (column 8, line 64-column 9, line 11).

Claim 31 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches comprising one or more icons, representing condition, phases, stages, level of authority and infusion parameters (icons used ad indicators of pump conditions, such as icon 72 and 74) (column 4, lines 41-52).

Claim 32 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the icons are selected from a group consists of sink representing the volume in the bag, syringe representing volume of dose or volume formerly infused (the display shown in Figure 18d represents the dose of the infusion) (column 13, lines 46-55).

Claim 33 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches at least one mobile icon, especially adapted to represent whether the pump is on or off and/or the progress of the infusion and/or the progress of any other command (a battery icon which indicates the progress of the pump, i.e. whether the pump is very charged or not very charged depending on the movable gauge of the battery icon, as shown in Figure 8a) (column 4, lines 41-52 and column 7, lines 28-34).

Claim 34 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches especially adapted to securely input numbers and digits, especially adapted to input infusion parameters and users IDS, comprising at least one predetermined portion of the page (i.e. zone) (using the key pad to enter number using the digits zero through nine, in order to enter values into highlighted fields) (column 3, line 64-column 4, line 11); each zone displays at least one digit (the display of digits in fields, such as the numbers displayed in the field shown in Figure 12).

Claim 35 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the zone representing the inputted digit is different from other zones while the user inputs the digit (user selected field for input are displayed differently, i.e. highlighted) (column 10, lines 1-4), by parameters selected from a group including color, size, shape, vibration of the zone frame, changing the width of the frame, marking the frame or any combination thereof (marking the frame, i.e. highlighting the field) (column 10, lines 1-4).

Claim 36 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the digits are inputted separately, by increasing and/or decreasing the number by one or more units of measure (the flow rate can be separately, i.e. independently increased or decreased by pressing the up or down keys) (column 10, lines 1-11).

Claim 37 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein messages are displayed upon inputting digits out of a predetermined range (alarms will be displayed to indicate that an entered value is outside of an allowable range/limit) (column 18, lines 17-41 and column 19, lines 16-30), providing the user with the possible range (the allowable limit, for example, the rate limit, is displayed in 28b).

Claim 38 lacks inventive step under PCT Article 33(3) as being obvious over Zaleski and Meinzer. Zaleski teaches all of the limitations as applied to claim 13 above. However, Zaleski fails to explicitly teach feedback mechanism, adapted to prevent faults that occur in case the user does not respond to a message or in case an inputted digit or number are out of normal range, or in case the user presses a button longer than a predetermined period of time. Meinzer teaches a graphical user interface for infusion pumps (Meinzer: column 2, lines 6-11) similar to that of Zaleski. In addition, Meinzer further teaches feedback mechanism, adapted to prevent faults that occur in case the user does not respond to a message or in case an inputted digit or number are out of normal range, or in case the user presses a button longer than a predetermined period of time (if parameters are out of range, an alarm will be activated) (Meinzer: column 8, lines 32-41). It would have been obvious to one of ordinary skill in the art, having the teachings of Zaleski and Meinzer before him at the time the invention was made, to modify the infusion pump GUI of Zaleski to include the feedback mechanism of Meinzer. One would have been motivated to make such a combination in order to provide the status of the infusion pump, allowing alerts and alarms to be displayed in order to notify the user of a problem and prevent failure.

Claim 39 lacks inventive step under PCT Article 33(3) as being obvious over Zaleski and Meinzer. Zaleski, as modified, teach the mechanism includes feedback means, selected from a group including LEDs, vocal response, pop-ups, and vibrations of the control unit, alerts, alerts to remote units, or any combination thereof (LEDs that flash to indicate alarm conditions) (Meinzer: column 5, lines 24-37).

Claim 40 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches constantly displayed icons, the icons represent the level of authorization, whether the bubble detecting mechanism is either ON or OFF and whether the pump is in progress or not (icon 72, part of the display device itself represent whether the mechanism is on or off, i.e. whether the device is plugged in or not) (column 4, lines 41-52).

Claim 41 lack novelty under PCT Article 33(2) as being anticipated by Zaleski. Zaleski teaches wherein enabling the user to change the display or location or size of at least a portion of the values displayed on one or more pages by marking appropriate fields or deleting the marking on the fields, especially in the view system page and any of the settings' or options' pages (the display of one of the values displayed on the GUI screen for setting values can be changed via altering the value, i.e. entering a new value) (page 3, paragraph 0022

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and page 4, claim 7).

Claim 42 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches enabling the user to add or remove content to or from the GUI, by transmitting one or more execute files to the CU using wired or wireless transmission (adding content, i.e. adding data to the pump from an external computer) (column 4, lines 49-52).

Claim 43 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein enabling the user to install or uninstall or update execute files or programs in the CU (downloading configurations to the infusion pump) (column 15, lines 52-64).

Claim 44 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches wherein the content is selected from languages, digits, icons, biometric tests, personalized specifications concerning the infusion parameters or any combination thereof (transferring infusion pump parameters, i.e. configurations by authorized personnel) (column 15, lines 52-64).

Claim 45 lack novelty under PCT Article 33(2) as being anticipated by Meinzer. Meinzer teaches messages displayed upon user's mistakes or incorrect input of infusion parameters (alarms will be displayed on the status display to indicate that an error, such as an entered value being outside of an allowable range/limit) (column 3, lines 50-52, column 18, lines 17-41 and column 19, lines 16-30) wherein the messages explain the user on the steps need to be taken such that the user's mission fulfilled (to fix the alarm, the user must enter a value within the limit, such as the limit shown in Figure 28b) (column 18, lines 17-41 and column 19, lines 16-30).

Claims 1-45 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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